K092810

SECTION 5

510(K) SUMMARY

NOV 18 2009

SUBMITTER:

r4 Vascular, Inc.
7550 Meridian Circle
Suite 150
Maple Grove, Minnesota 55369

ESTABLISHMENT REGISTRATION NUMBER:

3006242715

CONTACT:

Laurie Lewandowski
Director, Quality and Regulatory Affairs

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DATE PREPARED:

ENTER DATE

NAME OF MEDICAL DEVICE:

Proprietary Name:	Pherocious™
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
Common/Usual Name:	Long Term Intravascular Catheter

DEVICE CLASSIFICATION:

Classification Panel:	General Hospital
Regulatory Class:	II
Product Code:	LJS
Regulation Number:	21 CFR 880.5970

PREDICATE DEVICES:

Proprietary Name:	Hickman Long-Term Central Venous Catheter, Bard Hickman TriFusion
Common/Usual Name:	Long-Term Intravascular Catheter
Proprietary Name:	Zeus™ CT PICC
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC), single and double lumen

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DEVICE DESCRIPTION:

The r4 Vascular, Inc Pherocious™ is a family of apheresis triple lumen catheters designed to perform apheresis, intravenous infusion, blood sampling and power injection. The catheters, made of radiopaque polyurethane tubing are inserted via jugular, subclavian or femoral veins. Pherocious™ has a kink resistant, atraumatic, staggered tip design. The lumen with the purple connector, extension leg, and clamp may be used for CT injection as denoted by the text, "power injectable," printed on the extension leg. The remaining lumens with the red and blue connectors and blue and red or white clamps are for blood products. The catheters include female luer locking adapters and a tissue ingrowth cuff for fixing the catheters in a subcutaneous tunnel. The Pherocious™ kit includes a catheter and introduction components. The catheter is supplied sterile and non-pyrogenic.

The Pherocious™ product line has catheters in 10.5 Fr and 12.5 Fr triple lumen. The catheters come in a variety of lengths for patient specificity.

The Pherocious™ is similar to Bard TriFusion with the addition of the ability to CECT inject that is substantially equivalent to the Zeus.

INTENDED USE/INDICATION FOR USE:

The r4 Pherocious™ apheresis triple lumen catheter is designed for short and long term (>30 days) apheresis, intravenous infusion, blood sampling and CECT via the jugular veins or subclavian vein. The maximum recommended flow rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

New Device is compared to Marketed Device? Yes, it is compared to legally marketed predicates.

Does the New Device have the same indication statements? Substantially equivalent

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e., deciding may consider impact on safety and effectiveness)? No, difference do not alter the intended use of the device

Does the New Device have the same technological characteristics, e.g., design, material, etc.? Not in all regards. The principal of operation and basic design are the same as the predicate devices. The third lumen has been designed to enable CECT injection in addition to fluid delivery. CECT injection is substantially equivalent in performance to the Zeus CT PICC, one of the predicates.

Could the new characteristics affect safety or effectiveness? Yes. The changes may affect safety and effectiveness of the device.

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Do the new characteristics raise new types of safety and effectiveness questions? No. There are no new types of safety and effectiveness questions raised.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. Testing was based on FDA guidance documents and recognized standards to evaluate the devices' performance.

- The FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters,* dated 3/16/95 was used to determine the appropriate methods for evaluating the device's performance.
- ISO 10555-1:1997 Sterile, Single-use Intravascular Catheters, General requirements;
- ISO 594 Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment-Part1: General requirements
- ISO 10993 Biological Evaluation of Medical Devices Part-1: Evaluation and Testing

Biocompatibility requirements according to of ISO-10993, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.* Test profiles for externally communicating, blood-contacting, long-term devices will be met.

These and other standards were used to determine the appropriate methods for evaluating the device's performance.

Are performance date available to assess effects of new characteristics? Yes. Performance testing was generated in accordance with the above referenced guidance document and standards.

Do performance data demonstrate equivalence? Yes. Performance data gathered in design verification testing demonstrate that the Pherocious™ met the performance criteria of safety and effectiveness testing performed and based on the FDA's decision tree is substantially equivalent to the noted predicate devices.

CONCLUSIONS

The Pherocious™ met all established acceptance criteria for performance testing and design verification testing. This testing demonstrated that the Pherocious™ is safe and effective for its intended use, and based on FDA's decision tree is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Laurie Lewandowski
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R4 Vascular, Incorporated
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NOV 18 2009

Re: K092040
Trade/Device Name: Pherocious™
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: November 5, 2009
Received: November 6, 2009

Dear Ms. Lewandowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K092040

Device Name: Pherocious™

Indications for Use:

The r4 Pherocious™ apheresis triple lumen catheter is designed for short and long term (>30 days) apheresis, intravenous infusion, blood sampling and CECT via the jugular veins or subclavian vein. The maximum recommended flow rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.

Prescription Use: X AND/OR Over-the-Counter Use: _____
Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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